



## UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Lin Zhi *et al.* Art Unit : Unknown  
Serial No. : 10/566,569 Examiner : Unknown  
Filed : January 31, 2006 Cust. No. : 20985  
Title : 6-CYCLOAMINO-2-QUINOLINONE DERIVATIVES AS ANDROGEN Conf. No. : 6058  
RECEPTOR MODULATOR COMPOUNDS

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

Dear Sir:

Transmitted herewith are an Information Disclosure Statement, Forms PTO-1449 (6 pages), cited non U.S. patent references, and a return postcard for filing in connection with the above-identified application. Because this Information Disclosure Statement is filed prior to receipt of a first office action on the merits in the above-referenced application, no fee is due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No. 06-1050, as stated below:

- The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Stephanie Seidman  
Reg. No. 33,779

**Dated: July 11, 2006**

Attorney Docket No. 18202-030US1/ 1111US

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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**INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE  
WITH 37 C.F.R. §§ 1.97-1.98**

Because this Information Disclosure Statement is filed before the receipt of a First Office Action on the Merits for the above-captioned application, a fee for filing this statement should not be due. If, however, it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (6 pages) and copies of the cited non U.S. Patent documents are provided herewith.

The documents cited on the Forms PTO-1449 are in the English language, with the exception of items noted below. Item CJ (WO 01/27086) is in the Japanese language and is supplied with a Derwent abstract (item DM). Item CM (WO 02/22585) is in the Japanese language and an English language equivalent is listed (item AI). Item CV (DE 2334738) is in the German language and is supplied with a Derwent abstract (item DK). Item CW (DE 3810706) is in the German language and is supplied with a Derwent abstract (item DL) and a certified translation (item DH). Item CS (EP 0542609) is in the French language and is supplied with a Derwent abstract (item DJ). Item CF (WO 00/66680) is in the German language and an English language equivalent is listed (item CA). Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

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Serial No. : 10/566,569  
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Attorney's Docket No.: 18202-030US1/ 1111US  
Information Disclosure Statement

Applicant also makes known to the Examiner the following pending U.S. and International Applications that have one or more common inventors and/or are commonly owned:

<b>Docket No.</b>	<b>U.S.S.N.</b>	<b>Filed</b>	<b>Publ. No.</b>
002007/1002F	08/141,246	10/22/93	n/a
002009/1002H	08/141,496	10/22/93	n/a
002017/1002P	11/300,039	12/13/05	2006-0106072
066001/1022	08/958,727	10/27/97	n/a
040001/1025	08/377,423	01/23/95	n/a
004002/1026B	08/484,487	06/07/95	n/a
004003/1026C	10/847,732	05/17/04	2004-0209839
005003/1028C	10/360,580	02/05/03	20040019072
013003/1062C	11/340,282	01/25/06	n/a
015003/1073C	11/165,769	06/23/05	20050288350
017002/1081B	11/344,690	01/31/06	n/a
018001/1082	10/080,503	02/22/02	20020183314
020001/1088	10/684,229	10/10/03	20040152718
020002/1088B	11/411,676	04/25/06	n/a
030US1/1111US	10/566,569	01/31/06	n/a
035002/1059B	10/229,649	08/27/02	20030013766
048001/1087	10/684,212	10/10/03	20040152717
051RI1/1814RI	10/211,969	08/01/02	n/a
057001/1091	10/684,227	10/10/03	20040147530
057002/1091B	11/445,844	06/02/06	n/a

<b>Docket No.</b>	<b>Intl. No.</b>	<b>Filed</b>	<b>Publ. No.</b>
027WO1/1110PC	PCT/US2005/06627	02/24/05	2005/082909
028WO1/1112PC	PCT/US2005/07867	3/11/05	2005/090282
030WO1/1111PC	PCT/US04/027483	08/23/04	2005/018573

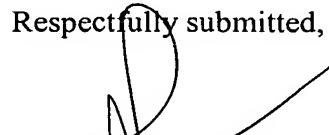
Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references or information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g and h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

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Serial No. : 10/566,569  
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Attorney's Docket No.: 18202-030US1/ 1111US  
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Applicant respectfully requests that the Examiner review the foregoing references and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

  
Stephanie Seidman  
Reg. No. 33,779

**Dated: July 11, 2006**

Attorney Docket No. 18202-030US1/ 1111US

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Sheet 1 of 6

Substitute Form PTO-1449 (Modified)		U.S. DEPARTMENT OF COMMERCE Patent and Trademark Office		Attorney's Docket No. 18202-030US1/1111US		Application No. 10/566,569	
<b>List of Patents and Publications for Applicant's Information Disclosure Statement</b> (37 CFR §1.98(b))							
<b>U.S. Patent Documents</b>							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2002/0094983	7/18/2002	Zhang, et al.	514	2305	12/17/2001
	AB	2002/0183314	12/5/2002	Higuchi, et al.	514	2245	2/22/2002
	AC	2002/0183346	12/5/2002	Zhi, et al.	514	291	2/22/2002
	AD	2003/0045511	3/6/2003	Grubb, et al.	514	141	5/9/2002
	AE	2003/0055094	03/20/2003	Sun, et al.	514	379	07/31/2002
	AF	2003/0149268	8/7/2003	Hamann, et al.	546	81	12/23/2002
	AG	2003/0186970	10/2/2003	Higuchi, et al.	514	2242	9/9/2002
	AH	2003/0216388	11/20/2003	Zhang, et al..	514	2305	3/12/2003
	AI	2003/216428	11/20/2003	Miyakawa, et al.	514	312	09/14/2001
	AJ	2004/0186132	9/23/2004	Jones, et al.	514	312	12/17/2003
	AK	2005/0288350	12/29/2005	Zhi, et al.	514	397	06/23/2005
	AL	3,847,988	11/12/1974	Gold	562	802	06/01/1973
	AM	3,928,686	12/23/1975	Poot, et al.	503	210	2/26/1973
	AN	3,979,394	9/7/1976	Janssens, et al.	546	77	3/5/1974
	AO	4,066,651	1/3/1978	Brittain, et al.	546	157	3/1/1976
	AP	4,097,578	06/27/1978	Perronet, et al.	514	389	10/21/1976
	AQ	4,138,490	2/6/1979	Brittain, et al.	514	312	9/12/1977
	AR	4,415,572	11/15/1983	Tominaga, et al.	424	250	10/30/1981
	AS	4,505,852	03/19/1985	Rasnick & Bissell	530	329	11/29/1982
	AT	4,636,505	01/13/1987	Tucker	514	256	07/15/1983
	AU	4,710,507	12/01/1987	Campbell, et al.	514	312	12/18/1984
	AV	4,728,653	03/1/1988	Campbell & Roberts	514	312	03/26/1986
	AW	4,933,336	6/12/1990	Martin, et al.	514	2225	8/9/1988
	AX	4,981,784	01/01/1991	Evans,et al.	435	6	11/30/1988
	AY	4,981,784	1/1/1991	Evans, et al.	435	6	11/30/1988
	AZ	5,071,773	12/10/1991	Evans,et al.	436	501	10/20/1987
	BA	5,071,773	12/10/1991	Evans, et al.	436	507	10/20/1987

Examiner Signature	Date Considered
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney's Docket No. 18202-030US1/1111US		Application No. 10/566,569	
<b>List of Patents and Publications for Applicant's Information Disclosure Statement</b>  (37 CFR §1.98(b))		Applicant Lin Zhi et al.					
		Filing Date January 31, 2006		Group Art Unit			
		<b>U.S. Patent Documents</b>					
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	BB	5,081,242	1/14/1992	Combs	544	52	2/15/1991
	BC	5,576,324	11/19/1996	Kyotani, et al.	514	291	10/27/1994
	BD	5,677,336	10/14/1997	Jones, et al.	514	546	10/21/1993
	BE	5,688,808A	11/18/1997	Jones, et al.	514	285	06/05/1995
	BF	5,688,810A	11/18/1997	Jones, et al.	514	311	06/05/1995
	BG	5,693,646A	12/02/1997	Jones, et al.	514	285	06/05/1995
	BH	5,693,647A	12/02/1997	Jones, et al.	514	285	06/05/1995
	BI	5,696,127A	12/09/1997	Jones, et al.	514	285	06/05/1995
	BJ	5,696,130A	12/09/1997	Jones, et al.	514	291	06/05/1995
	BK	5,696133A	12/09/1997	Jones, et al.	514	314	06/05/1995
	BL	5,977,108	11/2/1999	Kikuchi, et al.	514	249	12/30/1997
	BM	5,994,544A	11/30/1999	Jones, et al.	546	62	10/08/1997
	BN	6,017,924	1/25/2000	Edwards, et al.	514	292	8/12/1999
	BO	6,093,821	7/25/2000	Jones, et al.	544	333	10/8/1997
	BP	6,121,450	9/19/2000	Jones, et al..	546	81	10/8/1997
	BQ	6,180,794	1/30/2001	Edwards, et al.	546	152	10/15/1999
	BR	6,358,948	3/19/2002	Zhang, et al.	514	2305	4/19/2000
	BS	6,380,207	04/30/2002	Coghlan, et al.	514	285	02/13/1998
	BT	6,448,405B1	9/10/2002	Jones, et al.	546	62	10/08/1997
	BU	6,462,038	10/08/2002	Higuchi, et al.	514	224.5	08/25/2000
	BV	6,498,154	12/24/2002	Grubb, et al.	514	141	4/19/2000
	BW	6,506,766	01/14/2003	Coghlan, et al.	514	285	07/05/2000
	BX	6,534,516	3/18/2003	Edwards, et al.	514	285	11/24/1999
	BY	6,566,372B1	05/20/2003	Zhi, et al.	514	312	08/24/2000
	BZ	6,569,896	05/27/2003	Dalton, et al.	514	493	08/23/2001
	CA	6,635,759	10/21/2003	Uray and Niederreiter	544	128	12/31/2001
	CB	6,667,313	12/23/2003	Hamann, et al.	514	292	8/25/2000

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<b>U.S. Patent Documents</b>							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	CC	6,673,799	01/06/2004	Taniguchi,et al.	5142	5301	03/21/2001
	CD	6,696,459B1	02/24/2004	Jones,et al.	514	285	10/14/1997
	CE	6,964,973B2	11/15/2005	Zhi,et al.	514	312	11/18/2002

<b>Foreign Patent Documents or Published Foreign Patent Applications</b>							
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes      No
	CF	00/66680	11/09/2000	PCT			X+
	CG	01/16108A2	03/08/2001	PCT			
	CH	01/16133	3/08/2001	PCT			
	CI	01/16139	3/08/2001	PCT			
	CJ	01/27086	04/19/2001	PCT			X*
	CK	02/066475	8/29/2002	PCT			
	CL	02/068427	9/06/2002	PCT			
	CM	02/22585	03/21/2002	PCT			X+
	CN	0272910 A	06/29/1988	EP			
	CO	03/037905A1	05/08/2003	PCT			
	CP	0356230 A	02/28/1990	EP			
	CQ	05/018573A2	03/03/2005	PCT			
	CR	05/090282A1	09/29/2005	PCT			
	CS	0542609	5/19/1993	EP			X*
	CT	0638571	2/15/1995	EP			
	CU	2004/045518	6/03/2004	PCT			
	CV	2334738	01/01/1975	DE			X*
	CW	3810706 A	10/05/1989	DE			X
	CX	89/07441	8/24/1989	PCT			
	CY	94/23068A1	10/13/1994	PCT			
	CZ	96/19458A2	06/27/1996	PCT			

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							Yes	No
	DA	96/41013A1	12/19/1996	PCT				
	DB	97/49709	12/31/1997	PCT				
	DC	99/58486	11/18/1999	PCT				

X\*= An English language abstract is provided

X+= An English language equivalent is provided

**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
	DD	Alabaster, et al., "2(1H)-quinolinones with cardiac stimulant activity. 2. Synthesis and biological activities of 6-(N-linked, five-membered heteroaryl) derivatives." <i>J. Med. Chem.</i> , 32:575-583 (1989).
	DE	Bains & Tacke, "Silicon chemistry as a novel source of chemical diversity in drug design," <i>Curr. Opin. Drug Discov. Devel.</i> 6:526-43 (2003).
	DF	Berger et al., "Interaction of glucocorticoid analogues with the human glucocorticoid receptor," <i>J. Steroid Biochem. Mol. Biol.</i> , 41: 733-738 (1992)
	DG	Bissell et al., "Synthesis and Chemistry of 7-Amino-4- (trifluoromethyl) coumarin and Its Amino Acid and Peptide Derivatives," <i>J. Org. Chem.</i> , 45(12):2283-2287 (1980)
	DH	Certified English translation of German patent, DE 3810706 published 10/05/1989 entitled "Substituted Cumarine Derivatives, Method for their Production, and Their Use As an Application with an herbicide Effect."
	DI	Croston, G. E., Milan, L. B., Marschke, K. B., Reichman, M. and Briggs, M. R. Androgen receptor-mediated antagonism of estrogen-dependent low density lipoprotein receptor transcription in cultured hepatocytes <i>Endocrinology</i> 138(9):3779-3786 (1997)
	DJ	Derwert citing French patent EP 0542609 published 5/19/1993, for: "New 3-sulphonylamino-2(1H)-quinolinone derivs.- as excitatory aminoacid receptor blockers for treating cerebrovascular accident, spinal trauma, amyotrophic lateral sclerosis, Alzheimer's disease and schizophrenia."
	DK	Derwert citing German patent DE 2334738 published 1/1/1975, for: "Hair-dyestuff for oxidation-dyeing process-contg. 4 hydroxy-quinolone-2-derivs. as coupling components."
	DL	Derwert citing German patent, DE 3810706 published 10/05/1989, for: "New coumarin derivs. contg. imide gp.- useful as selective herbicides."
	DM	Derwert citing Japanese patent WO 01/27086 published 4/19/2001, for: "New tetrahydroquinoline derivatives useful as androgen receptor binding agents for treating e.g. males sexual dysfunction."
	DN	Edwards, et al., "5-Aryl-1,2-dihydro-5H-chromeno [3,4-f] quinolines as Potent, Orally Active, Nonsteroidal Progesterone Receptor Agonists: The Effect of D-Ring Substitutes," <i>Journal of Medicinal Chem.</i> 41:303-310 (1998).
	DO	Edwards, et al., "New nonsteroidal androgen receptor modulators based on4-(trifluoromethyl)-2(1H)-pyrrolidino[3,2-g] quinolinone," <i>Bioorg Med Chem Lett.</i> ,8(7)745-50 (1998)
	DP	Edwards, et al., "Nonsteroidal androgen receptor agonists based on4-(trifluoromethyl)-2H-pyrano[3,2-g]quinolin-2-one," <i>Bioorg Med Chem Lett.</i> , 9(7)1003-8 (1999)

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Other Documents (include Author, Title, Date, and Place of Publication)			
Examiner Initial	Desig. ID	Document	
	DQ	Edwards, et al., "Preparation, Resolution, and Biological Evaluation of 5-Aryl-1,2-dihydro-5H-chromeno[3,4-f]quinolines: Potent, Orally Active, Nonsteroidal Progesterone Receptor Agonists," <i>Journal of Medicinal Chem.</i> 41:2779-85 (1998).	
	DR	Evans, et al., "The Steroid and Thyroid Hormone Receptor Superfamily," <i>Science</i> , 240:889-895 (1998).	
	DS	Fingl et al. "The Pharmacological Basis of Therapeutics", Ch.1 p.1 (1975)	
	DT	Hamann, et al, "Discovery of a potent, orally active, nonsteroidal androgen receptor agonist: 4-ethyl-1,2,3,4-tetrahydro-6- (trifluoromethyl)-8-pyridono[5,6-g]- quinoline (LG121071)" <i>J Med Chem.</i> , 42(2):210-2 (1999)	
	DU	Hamann, et al. "Synthesis and biological activity of a novel series of nonsteroidal, peripherally selective androgen receptor antagonists derived from 1,2-dihydropyridono[5,6-g]quinolines.," <i>J. Med. Chem.</i> , 41(4) 623-639 (1998)	
	DV	Hamann, et al., "Nonsteroidal progesterone receptor antagonists based on aconformationally-restricted subseries of 6-aryl-1,2-dihydro-2,2,4-trimethylquinolines," <i>Bioorg Med Chem Lett.</i> , 8(19)2731-6(1998)	
	DW	Higuchi, et al., "4-Alkyl- and 3,4-dialkyl-1,2,3,4-tetrahydro-8-pyridono[5,6-g]quinolines potent, nonsteroidal androgen receptor agonists." <i>Bioorg Med Chem Lett.</i> , 9(9)1335-40.(1999)	
	DX	Kong, et al., "Effects of isosteric pyridone replacements in androgen receptor antagonists based on 1,2-dihydro- and 1,2,3,4-tetrahydro-2,2-dimethyl-6-trifluoromethyl-8-pyridono[5,6-g]quinolines," <i>Bioorg Med Chem Lett.</i> , 10(5)411-4.(2000)	
	DY	Labrie, et al., "Science behind total androgen blockade: from gene to combination therapy," <i>Clin. Invest. Med.</i> , 16: 475-492 (1993)	
	DZ	Lawson, et al., "Androgen responsiveness of the pituitary gonadotrope cell line LbetaT2," <i>J Endocrinol.</i> , 170(3)601-7.(2001)	
	EA	Luke, et al., "The Male Sex Accessory Tissues; Structure, Androgen Action, and Physiology," <i>The Physiology of Reproduction</i> , 1435-1487 (1994)	
	EB	Miner, J. N. and Tyree, C. M. "Drug discovery and the intracellular receptor family," <i>Vitamins and Hormones</i> , 62:253-280 (2001)	
	EC	Negro-Vilar A. Selective androgen receptor modulators (SARMs) a novel approach to androgen therapy for the new millennium. <i>J Clin Endocrinol Metab.</i> , 84(10)3459-62. (1999)	
	ED	Patel, et al., "Synthesis of substituted 6-(3',5'-dimethyl-1H-pyrazol-1'-yl) quinolines and evaluation of their biological activities" <i>Indian J. Chem.</i> , 29B:836-842 (1990).	
	EE	Pathirana et al., "Nonsteroidal human progesterone receptor modulators from the marine alga <i>Cymoplia barbata</i> ," <i>Mol. Pharm.</i> 47:630-635 (1995)	
	EF	Pooley, et al., "Discovery and preliminary SAR studies of a novel, nonsteroidal progesterone receptor antagonist pharmacophore," <i>J. Med. Chem.</i> , 41(18): 3461-3466 (1998)	
	EG	Rodbard, "Mathematics and statistics of ligand assays: an illustrated guide" In: J. Langon and J. J. Clapp, eds., <i>Ligand Assay</i> , Masson Publishing U.S.A., Inc., New York, pp. 45-99, (1981)	
	EH	Rosen, and Negro-Vilar, "Novel, non-steroidal, selective androgen receptor modulators (SARMs) with anabolic activity in bone and muscle and improved safety profile," <i>Journal of Musculoskeletal Neuronal Interactions/Journal of Musculoskeletal Neuronal Interactions</i> , 2(3):222-224 (2002)	

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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<b>List of Patents and Publications for Applicant's Information Disclosure Statement</b>  (37 CFR §1.98(b))		Applicant Lin Zhi et al.		
		Filing Date January 31, 2006	Group Art Unit	

**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
	EI	Rosen, et al., "Intracellular receptors and signal transducers and activators of transcription superfamilies - novel targets for small-molecule drug discovery," <i>Journal of Medicinal Chemistry</i> 38:25;4855-4874 (1995)
	EJ	Simental, et al., Transcriptional Activation and Nuclear Targeting Signals of the Human Androgen Receptor, <i>J Biol Chem.</i> , 266(1):510-518 (1991).
	EK	Singh et al., "Androgen receptor antagonists (antiandrogens): structure-activity relationships," <i>Curr. Med. Chem.</i> 7(2): 211-247 (2000)
	EL	Tacke & Zilch, "Sila-substitution — a useful strategy for drug design?" <i>Endeavour, New Series</i> , 10(4):191-197 (1986);
	EM	Tegley, et al., "5-Benzylidene 1,2-dihydrochromeno[3,4-f]quinolines, a novel class of nonsteroidal human progesterone receptor agonists," <i>J Med Chem.</i> , 41 (22):4354-9 (1998)
	EN	Walsh, et al., "Inhibition of extratesticular stimuli to prostatic growth in the castrated rat by antiandrogens," <i>Endocrinology</i> 86: 624 (1970)
	EO	Wen, D. X. and McDonnell, D. P. Advances in our understanding of ligand-activated nuclear receptors <i>Current Opinion in Biotechnology</i> 6(5):582-589 (1995)
	EP	Yin, et al., "Key structural features of nonsteroidal ligands for binding and activation of the androgen receptor," <i>Molecular Pharmacology</i> , 63(1): 211-223 (2003)
	EQ	Zhi et al. "Nonsteroidal progesterone receptor antagonists based on 6-thiophenehydroquinolines," <i>Bioorg Med Chem Lett.</i> ,10(5)415-418 (2000)
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	ET	Zhi, et al., "Switching androgen receptor antagonists to agonists by modifying C-ringsubstituents on piperidino[3,2-g]quinolinone," <i>Bioorg Med Chem Lett.</i> , 9(7)1009-12.(1999)
	EU	Zhi, L. and Martinborough, E. Chapter 17. Selective androgen receptor modulators (SARMs) <i>Annual Reports in Medicinal Chemistry</i> , 36:169-180 (2001)

Examiner Signature	Date Considered
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